

IN THE SPECIFICATION:

Please replace paragraph number [0001] with the following rewritten paragraph:

~~Field of the Invention~~

[0001] Field of the Invention: The present invention relates generally to apparatus for use in noninvasively measuring hematocrit and, more specifically, to apparatus which are configured to effect electrical impedance and pressure plethysmography techniques to noninvasively measure hematocrit. The present invention also relates to methods for manufacturing and using the components of the hematocrit measurement apparatus.

Please replace paragraph number [0002] with the following rewritten paragraph:

~~Background of Related Art~~

[0002] Background of Related Art: The “hematocrit” of blood, which is defined as the percentage of whole blood volume occupied by erythrocytes (*i.e.*, red blood cells), is an important measure of patient ~~well~~well-being in cases of trauma, blood loss by disease, iron depletion in pregnancy, dietary iron deficiency, and a number of more specific medical conditions.

Please replace paragraph number [0004] with the following rewritten paragraph:

[0004] The above-described methods for obtaining hematocrit are invasive in that they require that blood be removed from the patient in order to determine the hematocrit. Noninvasive techniques are desirable because they are less painful~~to~~to the patient and ~~less~~ inconvenient~~for~~for the patient.

Please replace paragraph number [0020] with the following rewritten paragraph:

[0020] In addition, the interface unit includes at least one pressurization component that communicates with the receptacle. The pressurization component may communicate with a pressure source to introduce a positive pressure into the receptacle such that the positive pressure

may be applied to at least a portion of a body part disposed within the receptacle. Like the one or more power sources, the pressure source may operate under control of a processing element, which may be the same as or different from that which controls the one or more power sources.

Please replace paragraph number [0021] with the following rewritten paragraph:

[0021] As an example of the use of interface unit includes assembling four electrodes with the interface unit such that the connection between the electrical contact of each electrode and ~~is~~ its corresponding contact of the interface unit is sufficient to facilitate electrical communication therebetween. In addition, the elongate element of each electrode is positioned so as to be located at least partially within the receptacle of the interface unit. The elongate elements of the electrodes may be arranged so that the conductive coating layers thereof will contact desired portions of a body part to be introduced into the receptacle. The body part of a subject may then be introduced into the receptacle in such a way that the conductive coating layers of the elongate elements of the electrodes are in contact therewith. Thereafter, additional contact may be established between the conductive coating layer on remaining portions of the elongate elements and the body part of the subject. Noninvasive measurement of the hematocrit of the subject, as known in the art, may then commence.

Please replace paragraph number [0025] with the following rewritten paragraph:

[0025] FIG. 2 is a cross-section taken along line 2-2 of FIG. 1, with a common contact ~~area~~ region of the pair of electrodes creased along a centerline thereof;

Please replace paragraph number [0027] with the following rewritten paragraph:

[0027] FIG. 4 is a ~~cross~~-cross-sectional representation of the strip shown in FIG. 3;

Please replace paragraph number [0041] with the following rewritten paragraph:

[0041] FIG. 18 is a ~~cross~~-cross-section taken along line 18-18 of FIG. 17;

Please replace paragraph number [0049] with the following rewritten paragraph:

[0049] Electrode pair 10 includes a common contact-~~area~~ region 12 and two elongate elements 14a and 14b extending therefrom. Elongate elements 14a and 14b may extend in substantially the same general direction and may be oriented parallel to one another. Each elongate element 14a, 14b includes an electrode 11a, 11b, each of which comprises a lateral extension-~~of~~ of, and electrically communicates with a corresponding electrical contact element 12a, 12b of common contact-~~area~~ region 12. As shown, elongate elements 14a and 14b may be substantially linear.

Please replace paragraph number [0056] with the following rewritten paragraph:

[0056] Further, the distance D by which elongate elements 14a and 14b are separated may be substantially the same as the width W of an elongate element 14a, 14b. Such a configuration facilitates the formation of electrode pairs 10 from a strip 40, depicted in FIG. 3, that comprises a laminate of insulative backing-~~layer~~ 20, conductive layer 24 covering portions of insulative backing-~~layer~~ 20 over which conductive structures are to be formed, and conductive coating layer 28, which extends substantially centrally along the length of strip 40, at a location from which elongate elements 14a and 14b of electrode pairs 10 will be formed.

Please replace paragraph number [0057] with the following rewritten paragraph:

[0057] As shown, strip 40 may include two opposed, offset rows 42 and 44 of electrode pairs 10A, 10B, 10C, etc., and 10A', 10B', 10C', etc., each of which comprises an electrode pair 10 (FIGs. 1 and 2). Common-~~contacts~~ contact regions 12 of electrode pairs 10 may be positioned and aligned along opposite long edges 41 and 43 of strip 40, with common-~~contacts~~ contact regions 12 of adjacent electrode pairs 10 of the same row 42, 44 being positioned adjacent to one another. Electrical isolation between adjacent electrical contact elements 12a and 12b of adjacent electrode pairs 10 occurs as the adjacent electrode pairs 10 are physically separated from one another.

Please replace paragraph number [0059] with the following rewritten paragraph:

[0059] As an example of a process for manufacturing strip 40, an insulative film (*i.e.*, insulative backing 20), a conductive film (*i.e.*, conductive layer 24), and a conductive coating (*i.e.*, conductive coating layer 28) may be laminated to one another by known processes. Optionally, as depicted in FIG. 4, strip 40 may include a support layer 38 upon which the other layers of the laminate are carried and from which the remainder of the laminate may be peeled and which may be formed from any suitable material known in the art (*e.g.*, a plastic-coated or wax-coated paper). Portions of conductive layer 24 may be removed, either before or after lamination is effected, to form discontinuities 26 (~~FIGs~~FIGs. 1 and 3). Following lamination, electrode pairs 10 and the various features thereof (including apertures 16) are formed and, thus, at least partially separated from one another.

Please replace paragraph number [0060] with the following rewritten paragraph:

[0060] By way of nonlimiting example, known die cutting processes may be used to form electrode pairs 10. Optionally, electrode pairs 10 and discontinuities 26 within conductive layer 24 thereof may be formed simultaneously, such as with a die that includes cutting edges of different heights (*i.e.*, a taller edge to define electrode pairs 10 and apertures 16 and a shorter edge to cut material out of conductive layer 24 to form discontinuities 26). If strip-~~30~~ 40 includes a support layer 38, electrode pairs 10 may be defined without cutting completely through support layer 38, which maintains the relationship of electrode pairs 10 until use thereof is desired.

Please replace paragraph number [0067] with the following rewritten paragraph:

[0067] Communication port 74 may comprise any known type of communication port, such as a multi-pin connection port, a USB port, a wireless port of a known type (*e.g.*, infrared (IR), radiofrequency (RF), etc.), or ~~other~~ the like. Communication port 74 provides an interface by which the electronic components that are carried by circuit board 72 may communicate with one or more output elements (*e.g.*, monitors, printers, etc.) or processing elements (*e.g.*, computer processors, computers, etc.) (not shown).

Please replace paragraph number [0068] with the following rewritten paragraph:

[0068] Componentry receptacle 66 may be enclosed by an access panel 79, which is configured to cover opening 65 and, optionally, facilitate access to componentry receptacle 66 and the elements disposed therein. In order to position access panel 79 flush with bottom surface 62 of base 60, an inset ledge 78 may be formed in bottom surface 62 around at least a portion of opening 65 of componentry receptacle 66. Inset ledge 78 is configured to receive access panel 79 without permitting access panel 79 to be inserted into componentry receptacle 66, as well as to facilitate securing of access panel 79 to base 60. Access panel 79 may be secured to base ~~90~~ 60 by any suitable technique. For example, bolts may be used to secure access panel 79 in place over opening 65, or it may be secured in place by way of one or more latches, a combination of hinges and latches, by way of a sliding mechanism, or otherwise.

Please replace paragraph number [0069] with the following rewritten paragraph:

[0069] A conduit 80 facilitates the communication of positive pressure from an external pressure source (not shown in FIGs. 7 through 9) to pressurization components 160 (FIGs. 17 through 19) that have been assembled with interface unit 50 (FIGs. 5 and 6), which will be described in further detail hereinafter. As shown, conduit 80 extends through base 60 between a desired location at an exterior surface thereof, such as an edge located adjacent to connection receptacle 68, ~~and~~ and a desired location on an upper surface 64 thereof. Both a first end 82 of conduit 80 that opens to connection receptacle 68 and an opposite, second end 84 of conduit 80 that communicates with upper surface 64 are configured so as to facilitate the coupling of hose barbs 85 or other pressure ports of known type thereto. By way of example only, ends 82 and 84 may be threaded so as to engage complementary threading on the exterior of hose barbs 85.

Please replace paragraph number [0072] with the following rewritten paragraph:

[0072] Monitoring element 90 is disposed on upper surface 64 of base 60. Monitoring element 90 includes two sides 94 and 98, which protrude generally upwardly from upper surface 64 of base 60. Each side 94, 98 forms a half 92a, 92b of receptacle 92. ~~End~~ Second

end 84 of conduit 80 is exposed to receptacle 92, for example, between sides 94 and 98, and may include a hose barb 85 of a known type disposed therein. Halves 92a and 92b of receptacle are configured to, in combination, receive at least a portion of a body part of a subject, such as a human finger. Each side 94, 98 also includes an upper edge 97, 101, respectively. Corresponding ends 95, 99 and 96, 100 of sides 94 and 98 respectively form a front 102 and a rear 103 of monitoring element 90.

Please replace paragraph number [0078] with the following rewritten paragraph:

[0078] Side 98 may likewise include guide pin receptacles 110' formed in ~~upper-surface~~ edge 101 thereof and guide pins 112' protruding from ~~upper-surface~~ edge 101. Guide pin receptacles 110' and guide pins 112', which may be aligned across receptacle 92 from corresponding guide pin receptacles 110 and guide pins 112, are useful for maintaining electrode pairs 10 (FIG. 21) that are adjacently positioned across receptacle 92 in electrically isolated relation to one another.

Please replace paragraph number [0082] with the following rewritten paragraph:

[0082] Cover 120 also includes a receptacle 122 which communicates with receptacle 92 of monitoring element 90. Like receptacle 92, receptacle 122 is configured to receive at least a portion of a body part. When the body part is disposed within receptacle 92 and cover 120 is appropriately positioned over monitoring element 90, receptacle 122 also receives a portion of the body part.

Please replace paragraph number [0083] with the following rewritten paragraph:

[0083] Cover 120 may be secured in position relative to one or both of monitoring element 90 and base 60. In the example of cover 120 shown in FIGs. 13 through 15, two connection elements 136 and 137 protrude downwardly from sides 124 and 128, respectively, at or near a rear 133 of cover 120. Connection elements 136 and 137 are located in planes which are substantially parallel to a length of cover 120. Each connection element 136, 137 includes an

~~apertures~~ aperture 138, 139, respectively, which is configured ~~align to align~~ with a corresponding aperture 116, 117 of a side 94, 98 of monitoring element 90 and, thus, to mutually receive a hinge pin 135 that has also been disposed through its corresponding aperture 116, 117.

Please replace paragraph number [0085] with the following rewritten paragraph:

[0085] If guide pins 112, 112' (FIGs. 10 and 11) that protrude from upper edge 97 are in ~~fixed position,~~ positions, pin receptacles 113 may be formed in biasing surface 127, as well as in the bottom edge (not shown) of side 128. Due to the hinged arrangement of cover 120 and monitoring element 90 in the depicted example, pin receptacles 113 are somewhat arced so as to facilitate their receipt of fixed guide pins 112.

Please replace paragraph number [0087] with the following rewritten paragraph:

[0087] As shown in ~~FIG.~~ FIGs. 13 through ~~15, 16,~~ when cover 120 is in a closed position over monitoring element 90, actuator handle 142 of locking element 140 may be biased toward rear 133 of cover 120 and rear 103 of monitoring element 90. As actuator handle 142 is moved in this fashion, locking arms 144 and 145 slide through their respective conduits 125 and 129 and the ends ~~146 and 147~~ 144E, 145E of locking arms 144 and 145 are introduced into apertures 116 and 117 of monitoring element 90, thereby locking cover 120 into a closed position over monitoring element 90. When opening of cover 120 is desired, actuator handle 142 of locking element 140 may be pulled away from rear 133 of cover, thereby moving locking arms 144 and 145 in the reverse direction through conduits 125 and 129 and out of apertures 116 and 117 of monitoring element.

Please replace paragraph number [0088] with the following rewritten paragraph:

[0088] Cover 120 may also be configured to facilitate the application of a positive pressure to a portion of a body part disposed within receptacle 122 thereof. For example, but not to limit the scope of the present invention, cover 120 may include a conduit 146 that extends from an exterior surface 121 thereof to receptacle 122. An end 147 of conduit 146 that opens to

exterior surface 121 of cover 120 may be configured to facilitate disposal of a tube 150 or other conduit in communication therewith. The other end 148 of conduit 146, which opens to receptacle 122, may be configured to facilitate placement of an air bladder or other pressurization component 160 (FIGs. 17 through 19) in communication therewith. By way of example, ends 147 and 148 may be threaded to receive complementary threading on hose barbs 149 or other pressure ports of a known type. Hose barbs 149 may be configured for coupling to a tube 150 or an inlet 166 (FIG. 19) of pressurization component 160. Thus, hose barbs 149 facilitate communication between a pressure source (not shown) that communicates either directly or indirectly with tube 150, ~~tube 150,~~ conduit 146, and pressurization component 160.

Please replace paragraph number [0090] with the following rewritten paragraph:

[0090] Pressurization component 160 includes a compliant bladder 162 of a known type, which includes at least two walls 163 and 164 that include peripheries that are secured to one another in an air-tight fashion (*e.g.*, by welds, adhesive, etc.), an interior 165 between walls, and an inlet 166 protruding from one of the walls (*e.g.*, ~~wall 163~~ 163).

Please replace paragraph number [0092] with the following rewritten paragraph:

[0092] Inlet 166, which may have a tubular appearance, facilitates the introduction of gases (*e.g.*, air) ~~into~~ into, and their removal from interior 165 of compliant bladder 162. An enlarged reinforcing base 168 may be disposed around an end 167 of inlet 166. Enlarged reinforcing base 168 may, along with suitable welds or adhesive material, securely fasten inlet 166 to wall 163.

Please replace paragraph number [0093] with the following rewritten paragraph:

[0093] Inlet 166 ~~configured~~ is configured to be coupled to hose barb 85, which is exposed to receptacle 92, or with a hose barb 149 of cover 120 (FIG. 13). Inlet 166 is formed from a somewhat compliant, somewhat resilient material, such as a urethane. Accordingly, when



inlet 166 is coupled to hose barb 85, 149, a substantially air-tight seal may be formed therebetween.

Please replace paragraph number [0098] with the following rewritten paragraph:

[0098] As shown in FIG. 21, two electrode pairs 10 or any other suitable arrangements of electrodes are positioned over receptacle 92, with conductive coating layer 28 being exposed (*e.g.*, facing upwardly) and a portion of each electrical contact element 12a and 12b contacting a corresponding contact 107 (FIG. 20) at upper edge 97 of side 94 of monitoring element 90. Rough alignment of contact elements 12a and 12b and their corresponding contacts 107 may be effected by positioning a guide pin 112 that protrudes from upper edge 97 through apertures 16 of electrode pair 10. Notably, elongate elements 14a and 14b of each electrode pair 10 remain spaced a substantially constant distance apart from one another, despite the positions of electrode pairs 10 relative to guide pins 112.

Please replace paragraph number [0100] with the following rewritten paragraph:

[0100] Additionally, elongate elements 14a and 14b of electrode ~~pair~~ pair 10 may be positioned on opposite sides of a guide pin 112' that corresponds to the guide pin 112 that extends through apertures 16 of electrode pair 10 and which protrudes from upper edge 101 of side 98 of monitoring element 90.

Please replace paragraph number [0101] with the following rewritten paragraph:

[0101] Of course, if pressurization of a body part to be introduced into receptacle 92 is desired, it is currently preferred that each electrode pair 10 be positioned over ~~receptacle~~ receptacle 92 following the positioning of a pressurization component 160, 160a therein.

Please replace paragraph number [0104] with the following rewritten paragraph:

[0104] Once elongate elements 14a and 14b of electrode pairs 10 (or other electrodes) have been positioned, cover 120 may be placed in a closed position over monitoring element 90,

as shown in FIG. 5. Locking element 140 may then be engaged, as described above with reference to FIGs. 13 through 16, to retain cover 120 in the closed position relative to monitoring element 90 and to ensure that an adequate electrical contact is made between each contact 107 of monitoring element 90 and its corresponding, adjacent ~~electrical-contact~~ elements 12a, 12b of electrode pairs 10.